REMARKS

In response to the Office Action dated December 13, 2002, the time for response having been extended by petition, Applicant submits the following. Claims 46, 61-62 and 64-67 are cancelled, without prejudice. Claims 47-60 and 63 remain in this application.

The Examiner rejected claims 48, 51, 60, and 62-67 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claims 48, 51, 54, 55 and 60 to fix the antecedent bases for the claimed elements listed by the Examiner and to more particularly point out and distinctly claim the inventions. As to claim 60, Applicant submits that the antecedent basis for what is now claimed as "said graft lumen" is found in the first line of the claim. Applicant submit that that the amendments overcome the 112 rejection and request the Examiner to withdraw the rejection.

The Examiner rejected claims 46-59 and 61-67 under 35 USC §101 because the claimed invention is directed to non-statutory subject matter. Applicant has cancelled independent claims 46 and 61, and the redundant dependent claims, without prejudice, and request that the Examiner withdraw this rejection.

The Examiner rejected claims 46, 49-55, 58-62, and 64-67 under 35 USC §102(e) as being anticipated by Slepian (US Patent No. 5,634,946). The Examiner relies primarily on two places in Slepian for support of the rejection: column 12, lines 9-12 for support that Slepian shows an anastomosis device; and column 10, lines 46-60 for support that such a device comprises a tubular member made of a deformable material, which is transformable upon application of energy between a non-fluent state and a fluent state in which the tubular member is radially expandable. Applicant traverses this rejection.

Slepian neither teaches or discloses the elements claimed in claim 60, or any of the claims depending therefrom. Instead, Slepian discloses an alternative to conventional stenting, an alternative that overcomes the problems caused by stents. Slepian states that

stents fail (at least in part) due to the compliance mismatch between the stent and the artery or the changes in fluid flow within the vessel created by the stent's presence. As Slepian states at column 4, lines 9-24:

> It has been observed that, on occasion, recurrent intravascular narrowing has occurred following stent placement in vessels during a period of several weeks to months. Typically, this occurs "peri-stent", i.e., immediately upstream or downstream from the stent. It has been suggested that this may relate to the often significantly different compliances of the vessel and the stent, sometimes referred to as "compliance mismatch". Aside from changes in compliance, another important mechanism leading to luminal narrowing above and below the stent may be the changes in shear forces and fluid flows encountered across the sharp transitions of the stent-vessel interface.

To overcome the perceived failings of stents, Slepian proposes to treat a tissue lumen or hollow space by paving or sealing the tissue lumen or hollow space with a polymeric material, called PEPS. PEPS, Slepian states, provides a closer compliance match with the vessel and its smooth surface does not change the shear forces or fluid flow within the vessel. Such a treatment involves applying the polymeric material to the interior surface of a blood vessel, tissue lumen or other hollow space, Slepian, col 4:55-61. Thus, at various places in the text, Slepian discloses using the polymeric material to seal or pave or coat or bandage a vessel surface.

In other words, Slepian discloses a means of treating different sites within a blood vessel but it does not teach or suggest Applicant's claimed invention. For example, Slepian does not describe or suggest, as claimed in claim 60, a fastener comprising a tubular member formed of a deformable material and sized and dimensioned for receiving an end portion of a graft lumen, the tubular member being transformable upon application of energy to the tubular member between a fluent state in which the tubular member is radially expandable to permit radial expansion of the graft lumen vessel, and a non-fluent state in which the tubular member retains the end portion of the graft lumen in its expanded state in sealing engagement with the target vessel.

The Examiner relies on language that Slepian mentions that "PEPS provides intraoperative uses such as sealing of vessel anastomoses during coronary artery bypass

grafting and the ability to provide a 'bandaged' smooth polymer surface". Slepian, col 12: lines 9-12. This passage, however, does not teach or suggest a device having a sleeve made of a material capable of being made fluent for connecting a graft lumen to a target vessel. The passage is consistent with the remainder of Slepian: PEPS is used to smooth or pave an inner surface of a vessel; in this case, where two vessels are joined, at the anastomosis site. In contrast, Slepian does not teach that PEPS is used ***to achieve the anastomosis*** by connecting or attaching the vessels together.

Slepian does describe forming its polymeric material as a sleeve, but Slepian forms a sleeve so that it is "readily insertable along with the catheter ***into*** the tissue lumen, and then to be deployed ***onto*** the wall of the lumen to form a coating." Slepian, col 10:lines 46-49. The sleeve of Slepian is inserted into a vessel and deployed onto the wall of the vessel lumen. Such a sleeve would not be sized and dimensioned to receive an end portion of a graft lumen. As a result, Applicant submits that the 102 rejection should be withdrawn as to the independent claim 60, and the claims that depend therefrom.

The Examiner further rejects claims 47-48 under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Nash et al (6,056,762); claims 56-57 under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Pathak (5,662,712); and claim 63 under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Hubbell (5,410,016). Each of these rejections relies upon Slepian as the primary reference. As a result, the combination of either Nash, Pathak or Hubbell with Slepian fails to teach or suggest the elements of the independent claims, or the dependent claims 47-48, 56-57 and 63, respectively.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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